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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/900,355 | 07/06/2001 | H. Craig Dees | PHO-122 | 5998 |

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| EXAMINER |
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EPPS FORD, JANET L

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| ART UNIT | PAPER NUMBER |
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1633

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| MAIL DATE | DELIVERY MODE |
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07/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 09/900,355 | Applicant(s) DEES ET AL. | |
| | Examiner Janet L. Epps-Ford | Art Unit 1633 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,9-11,36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,9-11,36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 July 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 9-11, and 36-37 are currently pending.

Drawings

3. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Figures 1a and 1b are structurally incorrect see the 112, 2nd rejection below. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.
- 4.

Response to Arguments

Claim Rejections - 35 USC § 103

5. The rejection of Claims 1, 9-11, and 36-37 under 35 U.S.C. 103(a) as being unpatentable over Heitz et al. for the reasons of record, and further in view of Walker et al. (US Patent No. 3,563,750), and Gee et al. is withdrawn in response to Applicant's amendment.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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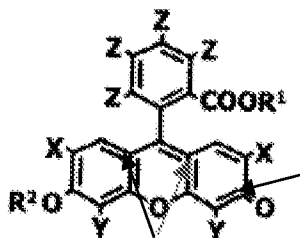
7. Claims 1, 9-11 and 36-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 1, 36-37, and those claims dependent therefrom, recite the limitation "wherein the functionalities at positions R^1 and R^2 each comprise an element selected from the group consisting of sodium, potassium and hydrogen.." However the metes and bounds of this limitation are vague and indefinite since the claims do not recite any formulas for 4,5,6,7-Tetrabromoerythrosin which comprise an R^1 or R^2 substituent.

9. Moreover, the actual structure of 4,5,6,7-Tetrabromoerythrosin is vague and indefinite since the specification as filed describes 4,5,6,7-Tetrabromoerythrosin in Table 1 as having an iodine atom at positions X and Y, bromine atom at position Z, and sodium at positions R1 and R2 as defined in Figure 1a. First, the instant claims are not limited to 4,5,6,7-Tetrabromoerythrosin as defined in Figure 1a or Table 1. The definition of this compound does not include wherein the substituents of R^1 or R^2 include potassium or hydrogen. Moreover, the structure in Figure 1a appears to be structurally incorrect:

Figure 1a recites the following:

Fig. 1a



The carbon atoms pointed out in the above Figure are involved in two separate double bonds and an additional single bond, this structure is chemically impossible as Carbon is known in the art to be capable of being involved in only 4 covalent bonds.

10. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for use of halogenated xanthene compounds for the treatment of tumor associated disorders, does not reasonably provide enablement for other non-tumor diseases and so called diseases of related organs recited in the instant claims, does not reasonably provide enablement for the treatment of liver, breast and renal tumor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

11. The instant invention directs to a medicament for use of treatment with certain diseases, wherein said diseases comprise "diseases of the skin and related organs, diseases of the mouth and digestive tract and related organs, diseases of the urinary and reproductive tracts and related organs, diseases of the respiratory tract and related organs, diseases of the circulatory system and related organs, diseases of the head and neck, diseases of the endocrine and lymphoreticular systems and related organs,

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diseases of connective tissues, diseases of tissue surfaces exposed during surgery, and diseases caused by microbial, viral, fungal, and parasitic infection.”

12. The primary compound used in the medicament recited in the instant claims is the 4,5,6,7-tetrabromoerythrosin.

13. The prior art of record, for example Goers et al. teaches that the halogenated xanthene Rose Bengal, which is structurally related to 4,5,6,7-tetrabromoerythrosin, functions as a photosensitizer and is activated by a light source and its cytotoxic effect is mediated through the production of singlet oxygen, which results in toxicity to neighboring cells (US Patent 4,867,973; col. 28, lines 45-68). The compositions of Goers et al. are disclosed as being specific for tumor treatment (col. 6, lines 22-28).

14. Applicant presents a plurality of prophetic examples in the specification as filed describing methods and potential medical uses of the subject medicament. In each case, the methods are summarized by the statement “these examples are provided for illustrative purposes, as the present invention is not limited to the recited examples and includes other indications known to those skilled in the art.” Furthermore, there is no particular example which demonstrates the use of 4,5,6,7-tetrabromoerythrosin in any particular method. Applicants present no data of respiratory, reproductive tracts, circulatory system, lymphoreticular system, or infections by microbial, viral, fungal or parasitic source has ever been shown. It is known that tumor biology is distinct from that of infection diseases caused by microbial, virus or parasites. Furthermore, different organs, such as liver, breast and kidney, are distinct from other organs and systems in regard to the anatomy, physiological and biological function. For instance, Horwitz et al.

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(US 5837677) have shown that using deferoxamine compound would be effective on breast cancer cells, but ineffective to brain tumor cell (neuroblastoma) and leukemia cell (Col. 1, line 15-30). One cannot extrapolate the limited tumor model to other non-tumor diseases and extend the scope of treatment to other physiological systems without undue experimentation.

15. In view of the aforementioned lack of predictability in the art, undue experimentation would be required to practice the claimed methods with a reasonable expectation of success, absent a specific and detailed description in the applicant's specification of how to effectively practice the recited treatments absent working examples.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/
Primary Examiner, Art Unit 1633

/J. L. E./
Primary Examiner, Art Unit 1633